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Self-Medication

Nonprescription Drug Manufacturers Association

May 1, 1990

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Director, Division of OTC Drug
Evaluation HFD-210
Office of Drug Standards
Center for Drugs & Biologics
Food & Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Bill:

I know you are aware of the problem which nonprescription drug manufacturers have in meeting the law's requirements that all required information be on the label in a way which is legible, especially to visually impaired persons (elderly or not).

A recent California bill has addressed this and has occasioned the Nonprescription Drug Manufacturers Association to re-focus our attention on this matter. This has resulted in the promulgation of guidelines for industry, guidelines which have been mailed to all member companies asking that they review their product line against six criteria to see if there can be improvements made in legibility.

I know that you, as head of the OTC Division of the Food and Drug Administration, are contacted about this matter from time to time, and I felt it would be useful if you were aware of our current efforts -- efforts I believe will result in improvements in legibility of OTC labels.

Sincerely,

James D. Cope President

JDC/mp

Enclosure: NDMA "Points For Consideration In Examining Product Labels for Readability and Legibility"

90P-0A01

Nonprescription Drug Manufacturers Association

Points For Consideration In Examining Product Labels for Readability and Legibility

The Nonprescription Drug Manufacturers Association (NDMA) Manufacturing Controls Committee and staff have discussed label/labeling legibility and readability, and provide the following list of points for NDMA members to use in making sure their product label is as legible as possible.

The package of each size of each product should be examined with the following in mind, with a view toward improving legibility:

- 1. General legibility. Read your own labels. Examine the presentation of your labeling information as would a consumer. Is it readable?
- 2. <u>Utilization of available space</u>. In some cases it may be possible to enlarge label type size by extending the copy into some of the existing "white space." Examine the location and placement of information. Review alternative approaches to maximizing available space allocation, including placement of directions, instructions, warnings and precautions on more than one panel of exterior carton.
- 3. Contrast and color. Review not only the size and placement of information, but also review the utilization of color and contrast to emphasize and draw attention to labeling information. Highly contrasting copy/background colors are more legible than low contrast colors. Dark type on a light background is more legible than light-on-dark. The smaller the type, the greater the contrast should be. Consumers of all ages are more apt to read and understand label information presented in a sharp contrast.
- 4. Style of print. Examine possible variations in style of type and graphic presentation. Upper and lower case type is easier to read than all capitals. Plain block print is more legible than fancy type. Allow space between paragraphs and words. Indent, bold and highlight information such that it will grab the attention of the consumer and focus attention on label information.
- Ouality of print. Size of type is not everything. The quality (sharpness) of print has a great effect on legibility. Different printing methods differ in quality, e.g., letterpress printing is usually sharper than offset. Thinner (less bold) type may appear sharper than bolder type.
- 6. Package innovation possibilities. Creative packaging can provide more space for information, allowing more flexibility in presentation of information. Think of ways that would assist a consumer in reading and understanding label information.